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Original Research

Effects of orthopedic instruments breakage during surgery: A minimum five-year follow-up

Effects of orthopedic instruments breakage during surgery

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Abstract

Aim: The present study aims to investigate the the long-term effect of metallic orthopedic instruments that were broken and not removed during surgery on the health status of patients.

Results: The rate of orthopedic instrument breakage during surgery was 0.28%. This was 0.64% in trauma cases and 0.08% in elective surgery cases. The broken instrument was a Kirschner wire (K-wire) in 16 (44.4%) cases, a screw in 14 (38.9%), and a drill bit in 6 (16.6%). The rate of instrument breakage was 7.44 times higher in trauma cases than in elective surgery cases, which was statistically significant (p = 0.001). Only 1 patient required reoperation for the broken instrument 7 years later. No surgical notes regarding broken implants were identified in patient files.

Discussion: Instruments that are broken and not removed during surgery do not cause any complication if they are entirely within the bone. Nevertheless, any instance of instrument breakage should be documented, and the patient should be informed about the condition and followed closely.

Keywords

Drill Bit; Kirschner Wire; Broken Sew; Malpractice; Complication

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Material and Methods: Radiographs of 12,601 patients (5765 females and 6836 males; mean age: 48.9 years; range: 0-105) who underwent orthopedic surgery in our clinic between January 2009 and January 2015 were screened. Thirty-six patients (13 females and 23 males; mean age: 45.3 years; range: 12-82) with metallic instruments, broken and not removed during surgery, were included in the study and minimum five-year follow-up radiographs of the patients were examined.

Introduction

There is an unwritten bond of trust between physicians and patients, and this forms the basis of medicine. Physicians are required to consider the benefit of the patient to the greatest extent possible in every procedure they perform and adhere to the principle of primum non nocere. This should serve as a guideline, especially in decisions involving unexpected complications that may arise during surgeries. The most common material broken during surgical operations is the drill bit with 40%, followed by hand tools with 26%, needle tip with 18%, guidewire with 7%. It has been reported that failure to remove the broken metallic implant does not cause serious complications in the patient [1]. However, FDA USA reported that nearly 1000 cases were reported annually, and implants that were not removed in these cases could cause complications, including infection, local reaction and even death [1].

In the literature, the rate of instrument breakage during orthopaedic procedures has been reported to be between 0.18% and 0.35%. [2, 3] In general, the broken instrument must be removed if it is (i) embedded in soft tissue, (ii) adjacent to or in contact with the joint, (iii) adjacent to neurovascular structures, or (iv) intersecting both cortices of the bone [2]. If it is estimated that the surgical time for the removal of the instrument fragment may adversely affect the patient's health and entail further complications, the surgeon may opt not to remove the substance. There are case reports indicating that instruments broken during or after surgery can cause serious complications and even death [4, 5].

The recent increase in malpractice lawsuits in Turkey and worldwide has led to a reconsideration of decisions taken during surgeries, especially concerning patient health. The present study aims to investigate the effects of orthopedic instruments that were broken and not removed during surgery on the health status of patients over a five-year period.

Material and Methods

Initially, 18,578 patients who were operated in the Orthopaedics and Traumatology Department of the Faculty of Medicine between January 2009 and January 2015 were included in the study. Outpatient surgeries (closed reduction, soft tissue tumor removal, carpal tunnel syndrome treatment, etc.) were then excluded. Postoperative radiographs of the remaining 12,601 patients (5765 females and 6836 males; mean age: 48.9 years; range: 0-105) were examined. Location and number of fragments of metallic instruments that were not planned to remain in the patient's body before the operation, the type of surgery performed for the removal of the fragments, and the seniority of the surgeon performing the operation were recorded on these radiographs taken in the operating room. Six patients with a follow-up less than five years and 4 patients who had died within five years after surgery were excluded from the study. Any changes in the location of fragments observed in the follow-up radiographs that were present in our hospital archives were recorded, as well as any additional surgical procedures undergone due to the fragments. The patients who were not followed up in our hospital were tracked through the Turkish national personal health record system.

The study was conducted in accordance with the Declaration of

Helsinki. Approval was obtained from the University Research and Ethics Committee (Project Number: KA19/346).

Statistical Analysis

Binary logistic regression was conducted to estimate the odds ratio (OR) and 95% confidence interval (Cl). Statistical analysis was performed with SPSS Statistics for Windows, Version 24.0. A p- value < 0.05 was considered statistically significant.

Results

Breakage of an orthopedic instrument occurred in 36 (0.28%) of 12,601 cases (8095 elective surgery cases, n = 13, 0.08%; 4506 trauma cases, n = 23, 0.64%). The mean follow-up time for these cases was 7.4 years (range: 6-13 years). The rate of instrument breakage was 7.44 times higher in trauma cases than in elective surgery cases (p = 0.001).

The broken instrument was a K-wire in 16 (44.4%) cases, a screw in 14 (38.9%), and a drill bit in 6 (16.6%). In 1 patient, a second surgery was required due to a broken drill bit. In 4 patients who underwent revision surgery for screws with broken heads, it was decided during the procedure that the removal of the broken instrument was not necessary. However, no remarks were found in the medical records to indicate that the patients were informed about the broken instruments. In 12 of 16 cases with broken K-wire, the breakage was in the drill guide pin used for the cannulated screw (Figure 1). All cases with a broken drill bit had undergone minimally invasive trauma surgery. A comparison of the patients with instruments broken during surgery and the control group is given in Table 1. Among the cases with a broken drill bit, fragments were detected in the proximal humerus in 3, in the pelvis in 1, in the tibia in 1, and in the femur in 1. In all 3 cases, in the proximal humerus, the drill bit fragments were located at points fit for the calcar screw (Figure 2). Among the 14 cases with broken screws, 8 were elective surgery and 6 were trauma. The rate of orthopedic instrument breakage in male patients was twice that of female patients, but no statistically significant difference was observed compared with the control group (p = 0.34). Also, there was no relationship between the age of the patients and the seniority of the surgeon performing the operation. The distribution of broken implants with respect to bones was as follows: 13 in the femur, 8 in the humerus, 8 in the tibia, 4 in the pelvis, 2 in the calcaneus and 1 in the metacarpal. In other words, 27 (75%) of the broken implants were in the lower extremities and 9 (25%) in the upper extremities.

Table 1. Comparison between the case group with instruments

 broken and not removed during surgery and the control group

| Variable | Case Group (n=36) | | Control Group (n=12601) | | OR [95%CI] | Ρ |
|---|----------------------|------|----------------------------|------|-------------------|--------|
| | Mean ± SD | | Mean ± SD | | | |
| Age | 45.28 ± 19.47 | | 48.95 ± 23.01 | | 0.99 [0.98-1.01] | 0.340 |
| | Number | % | Number | % | OR [95%CI] | Р |
| Gender | | | | | | |
| Male | 23 | 63.9 | 5765 | 45.8 | 2.01 [1.06-4.15] | 0.033 |
| Female | 13 | 36.1 | 6836 | 54.2 | 1 (reference) | 0.035 |
| Surgery | | | | | | |
| Elective | 7 | 19.4 | 8095 | 64.2 | 1 (reference) | 0.001* |
| Trauma | 29 | 80.6 | 4506 | 35.8 | 7.44 [3.26-17.00] | 0.001 |
| *Statistical significance: 0.05; Binary logistic regression analysis. * SD: Standard deviation * OR: Odds ratio | | | | | | |



Figure 1. A. Postoperative radiograph of trimalleolar fracture, the breakage was in the drill guide pin used for cannulated screwB. Postoperative radiograph of bimalleolar fracture, the breakage was in the drill guide pin used for cannulated screw



Figure 2. A. Postoperative radiograph of proximal humerus fracture, the drill bit fragments were located at points fit for calcar screwB. Postoperative radiograph of proximal humerus fracture, the drill bit fragments were located at points fit for calcar screw

Discussion

The patient filed lawsuits considering the failure to remove orthopedic implants broken during surgery as part of malpractice. In these cases, patients demand serious compensation because the implants broken during surgery seriously affect their lives. Our study, which was conducted to clarify these claims, showed that the implant broken in the bone does not adversely affect the patient's health in the long-term.

In the present study, orthopedic instrument breakages occurring during surgery were mostly in trauma cases and in the lower extremities and long bones, which was in line with the literature [2, 3]. Although there are numerous case reports elaborating on life-threatening complications due to implants broken during surgery, we did not come upon such conditions in our case series.

Price et al reported a 0.18% rate of instrument breakage in their study [3]. The rate was 0.03% in elective cases and 0.79% in trauma cases. Among the 14 broken instruments, 11 were drill bits, and 8 of the surgical cases were performed by residents. In 7 cases, the fragment was removed during surgery, but patients in most cases were not informed about the situation.

In a multicenter study by Pichler et al, the rate of implant breakage was 0.35% [2]. The fragment was removed in 5 cases and left in situ in 7. No complications were encountered in the cases without removal. However, only in 3 out of the 7 cases, the situation was recorded in the operation note. The investigators of the study underlined the necessity of documenting implant breakages.

The present study determined a rate of instrument breakage similar to both studies above. One major reason for the breakages may be that drill bits and guide wires, which should normally be single-use, are sterilized and reused in general orthopedic practice. As mentioned above, implant breakages were more common in trauma cases, and this is apparently related to the frequent use of drill bits and K-wires in surgery. The investigators also realized that the instruments that were broken and not removed during surgery were left undocumented, possibly meaning that patients were not informed either. This may entail a high risk of legal problems in the future.

K-wires without fixation to the bone must be removed due to their tendency to migrate into soft tissue. There are publications reporting cases of unremoved K-wires in soft tissue that are later extracted from the esophagus, abdominal cavity, spinal cord and brachiocephalic artery [6-9]. In the present study, there was migration of a broken drill bit in 1 case, and the fragment was removed without causing neurovascular complications. Examination of postoperative radiographs of the patient revealed that the fragment was not entirely within the bone cortex and had soft tissue penetration.

It seems likely that limited surgical approaches due to the increasing popularity of minimally invasive intervention in the last 20 years have played part in breakages of drill bits and K-wires. In the present study, in 3 cases with broken drill bits located in the proximal humerus, the fragments corresponded to the alignment of the calcar screw. This suggests that the screw may have been inserted at a tight angle with a minimal incision so as not to damage the axillary nerve adjacent to the insertion point. Similarly, the fragments of drill bits broken in the posterior acetabular surgery and tibia plateau posterior approach were found aligned with the distal holes of the plates. In the cases with broken K-wire, the breakage was in the guide pin used for cannulated screw placement. A major reason for guide pin breakage is repeated use, which causes deformation,

resulting in reduced flexibility and diminished torsion strength [10]. The guide pin direction may be distorted while passing through bones of differing densities or during transition through a joint, in which movement of the joint during fixation, or pin deflection crossing the joint space, creates a slight change in direction. The deformation of direction may impede smooth passage of the drill bit over the guide pin and can erode the pin, creating a stress that results in breakage. Roy et al. have described a minimally invasive technique for the retrieval of broken guide pins using a cannulated drill [11]. However, it is risky to use this technique in regions such as hip and pelvis, where the neurovascular structures are concentrated. In the case report by Afshar et al., a cannulated screw placed adjacent to the joint for the fixation of femoral neck fracture caused breakage of the K-wire and its ensuing advance into the pelvis. Through the ilioinguinal approach, a wire fragment was retrieved from the pelvic surface of the acetabulum [4].

Screw head breakage, especially when removing locking screws, is not an uncommon complication. Special sets and techniques have been developed to remove a screw with a broken head [12]. The working principle of these sets is based on drilling a hole around the remaining shaft larger than its diameter and clenching the shaft with another instrument. However, the hole drilled during this process may indeed weaken the cortical bone. In addition, the removal of each broken screw increases the operating time.

Broken metallic instruments should be routinely removed if the remaining fragment is within the bone, not in contact with the joint space, and not adjacent to neurovascular structures. The surgeon should properly assess the type of operation, the time and effort required to remove the fragment, and any complications that may arise during and after the procedure Our investigation did not substantiate that broken implants not removed during surgery necessarily lead to complications and second surgeries. In our series, there was only 1 case with a broken drill bit, which required revision surgery. It is probable that the perioperative assessment was not duly performed in this particular case.

Drill bits used during the surgery are single-use. If the torque on the drill is too large, the drill may tend to jam or even to break in the bone [12, 13]. Reuse of drills bits may result in metal fatigue and, in turn, breakages. Higher rate of drill bit breakage in our case series compared to the literature may be associated with this phenomenon.

According to the results of our investigation, screw fragments in the bone due to head breakage did not cause complications in the long haul. However, broken screws are encountered in patients with implant failure due to various reasons after plate osteosynthesis technique applied with screws in long bone fractures. In a long bone fracture that failed to heal, it is necessary to remove all screw fragments in the canal with an intramedullary nail (IM nail) prior to the revision procedure. **Study Limitations**

A major limitation of the present study is the uncertainty regarding the exact number of cases where instruments are broken and not removed during surgery. Another limitation is that it is not clear how many times the drill bits and K-wires had been used prior to breakage. Availability of this particular data would enable more accurate results in investigation. Another limitation of our study is that it is not known whether metallic implants that have not been removed cause a problem in patients' magnetic resonance imaging. There is no data on whether this situation is a problem for patients or not.

Conclusion

In conclusion, the rate of orthopedic instrument breakage in the present study was in line with the literature. Although remaining fragments in the patient's body did not cause severe complications, according to our case series, perioperative assessment should be duly performed, the situation should be properly documented and the patient should be informed within the framework of a sound physician-patient relationship. In addition, these patients should be followed closely in order to ensure early diagnosis of possible complications.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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